

Adherence With Allergen Immunotherapy Labeling Guidelines

Marilyn Karam, MD^a, Kiela Samuels, Pharm D^{a,b}, Christine Holland, MD^a, Cynthia Hernandez, RN^c, and Matthew Greenhawt, MD, MBA, MSc^{a,d} Ann Arbor, Mich

What is already known about this topic? There are exceptionally limited data that assessed prescribers' adherence to allergen immunotherapy labeling guidelines.

What does this article add to our knowledge? This study highlights poor adherence to allergen immunotherapy extract vials labeling guidelines and notes this as a potential function of the number of years in practice.

How does this study impact current management guidelines? This study highlights the potential for adverse events that could result from nonadherence to allergen immunotherapy extract vial labeling guidelines and raises questions about reasons of nonadherence and ways to best implement practice guidelines.

BACKGROUND: Little is known about the adherence rate to allergen immunotherapy (AIT) labeling guidelines.

OBJECTIVE: To assess adherence to labeling guidelines of AIT Practice Parameter 2011 at University of Michigan Health Service.

METHODS: AIT vials of 320 patients who received their care at the University of Michigan Health Service were reviewed. Data

collected looked at patient identifiers (PI), concentrations in volume/volume (v/v) format, color coding, allergen content, expiration date and instructions about AIT dosing, and systemic reaction treatment. Data were analyzed by using χ^2 test and the Fisher exact test and logistic regression.

RESULTS: Of 238 non-university formulated labels, 65% had 2 PIs, 62% had a v/v concentration, 41% had color coding, 71% had the content listed, and 100% had a recorded expiration date. Only 21% had all 5 recommended components. All 82 University vials had 5 components. Labels with 2 PIs were more likely to have a v/v concentration with its corresponding color coding (odds ratio [OR] 3.84 [95% CI, 1.9-7.7]; $P < .001$). Labels that specified the extract's content were more likely to be color coded or to have a v/v concentration listed (OR 6.3 [95% CI, 3.4-11.8]; $P < .001$). For all AIT vials, complete labels were significantly more likely to have a clear buildup schedule (OR 9.6 [95% CI, 4.2-23.2]; $P < .001$), dosing adjustment after a missed dose (OR 8.2 [95% CI, 3.4-19.8]; $P < .001$) or after a reaction (OR 13.7 [95% CI, 7.8-2.1]; $P < .001$), and clear systemic reaction treatment instructions (OR 9.7 [95% CI, 7.8-24.1]; $P < .001$).

CONCLUSION: Fewer than 25% of the nonuniversity prescribers adhered to AIT practice parameters 5 years after publication. Recording 2 PIs, the v/v concentration, or the color coding increased the likelihood of having a complete label. Complete label contents were associated with clear instructions about AIT dosing and reaction treatment and/or dose adjustments. © 2014 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2015;3:250-5)

Key words: Allergen immunotherapy; Practice parameters; Practice guidelines; Immunotherapy labeling; Allergen extracts; Student health services; Adherence; Health services research

Allergen immunotherapy (AIT) was first used successfully in 1911 by Noon,¹ who noticed an association between allergic symptoms and the grass pollination season in England. Recent advances in the clinical application of AIT, as recommended by recent practice parameters, have aimed to significantly improve

^aDivision of Allergy and Clinical Immunology, Department of Internal Medicine, University of Michigan Health System, Ann Arbor, Mich

^bUniversity of Michigan School of Pharmacy, Ann Arbor, Mich

^cUniversity Health Services, University of Michigan, Ann Arbor, Mich

^dChild Health Evaluation and Research Unit, Division of General Pediatrics, Department of Pediatrics, University of Michigan Medical School, Ann Arbor, Mich

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Corresponding author: Matthew Greenhawt, MD, MBA, MSc, Division of Allergy and Clinical Immunology, The University of Michigan Medical School, 24 Frank Lloyd Wright Dr. Lobby H-2100, Box 442, Ann Arbor, MI 48106. E-mail: mgreenha@med.umich.edu.

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Abbreviations used

AIT- Allergen immunotherapy

CC- Color coding

Exp- expiration date

OR- Odds ratio

PI- Patient identifier

UHS- University Health Services Center

UM- University of Michigan

v/v- Concentration in volume/volume

AIT quality and its clinical outcomes,²⁻⁵ AIT clinical outcomes require the provision of high quality and safe AIT extract preparation and labeling. There has been an iterative process in terms of expanding labeling guidelines during the past 11 years and now 3 sets of published AIT guidelines exist,²⁻⁵ most recently the third AIT practice parameter update published in 2011.⁵ Additional up-to-date references are available for the AIT prescriber and the preparers of AIT extracts, in addition to the practice parameters, including allergen extract manufacturer preparation manuals: the Allergen Immunotherapy Extract Preparation Manual, and the United States Pharmacopeia's General Chapter 797 (USP 797).⁶⁻¹¹

The guidelines recommends that all extract vials label should contain 2 or more patient identifiers (PI),²⁻⁵ the expiration date or beyond use date,²⁻⁵ abbreviations or names of allergen content, or a link to a document that lists specific allergen content.²⁻⁵ Labels also should include the concentration of each vial listed in a volume-to-volume (v/v) format, with 1:1 indicating the maintenance concentrate. During the buildup phase of immunotherapy, 4 (and, in some instances, 5) dilutions of the patient's maintenance concentrate are needed. The guidelines recommends using a color-coding system with a red cap that indicates the 1:1 v/v concentrate, yellow for the 1:10 v/v, blue for the 1:100 v/v, green for 1:1000 v/v, and silver for the 1:10,000 v/v dilution (if a fifth dilution is necessary).²⁻⁵ It also is permissible, per the practice parameter recommendations, to use an alphanumeric system that begins at "1" or "A" for the maintenance vials or to list the concentrations of allergens in each vial as alternative labeling methods.³⁻⁵ However, these may be a source of confusion for health care personnel who administer allergy injections, especially if one chose to label in a reverse order with "5" being the concentrate.

The effects of labeling variation, or errors that result from such labeling variation, have not undergone robust prior study. Differences in labeling of AIT extracts can potentially lead to confusion, dosing errors, and increased systemic reactions in nonallergy health care settings (such as a primary care office or college health clinic) who administer but do not prescribe AIT. Such settings handle AIT written by numerous, differing providers (from both allergists and otolaryngologists), which may not be similar in style and have to handle high degrees of labeling disparities that may potentially exist. We thus conducted a study at the University of Michigan (UM) University Health Services Center (UHS) to determine the rate of adherence of non-UM referring prescribers of patients who receive AIT at UHS to the AIT practice parameters guidelines. UHS is a health clinic that services the UM undergraduate and graduate campuses, and provides the opportunity for patients to continue to receive AIT injections from multiple independent providers by using their originally prescribed and mixed serum extract.

METHODS

AIT extract vials labels of all 320 patients who received their care at UHS during the fall of 2013 were reviewed. UHS is a health care clinic located on the central campus of UM. It is accredited by the Accreditation Association for Ambulatory Health Care Inc, a nationally recognized organization. With approximately 80,000 total visits per year and approximately 5000 AIT injection visits per year, UHS is a highly used campus resource. UHS services are available to any enrolled undergraduate and graduate student, faculty and staff, retirees, alumni, and spouses and domestic partners and dependents of these individuals. All AIT extract vials of patients who receive their injections at UHS are stored in alphabetical order in 1 refrigerator. Labels of all 320 available AIT extract vials in the storage refrigerator were checked for the different elements recommended by the third update AIT practice parameter, including the following:

- Two PIs, including the patient's full name, date of birth, and medical record number²⁻⁵
- Concentration of the vial in v/v format²⁻⁵
- Allergen content, whether or not abbreviated²⁻⁵
- Expiration or beyond use date²⁻⁵
- Color or an alphanumeric coding system that indicates a dilution from the corresponding maintenance concentrate vial³⁻⁵

Corresponding medical records for each AIT extract vial were screened for the presence of a clear buildup schedule stipulated by the prescriber as well as for the presence of instructions and/or guidance of a clear definition of the signs of a reaction, treatment instructions of a local or systemic reaction, clear instructions about AIT dosing adjustment after a reaction, and clear instructions on dosing adjustments after a missed scheduled dose. All the data were recorded into an Excel spreadsheet (Microsoft Corp, Redmond, Wash) for data keeping. Finally, we performed a Web-based search of each provider listed for the external prescribers by using the American Board of Medical Specialties (www.abms.org, for allergy/immunology and for otolaryngology) and both the American Academy of Allergy, Asthma & Immunology (www.aaaai.org) and the American College of Allergy, Asthma and Immunology (www.acaai.org) Web sites to determine the number of years that each prescribing provider has been in practice. AIT written by UM allergy/immunology faculty were not included for final analysis, per prespecified intent, because all UM allergy/immunology prescribed labels are adherent with the 5 components of the labeling guidelines described in the bullet points above.

The specific outcomes of this study were to determine the extent to which external providers to UHS complied with labeling guidelines and assess factors associated with labeling adherence. The data were uploaded from the Excel spreadsheet into Stata 13 SE (StataCorp, College Station, Tex) and analyzed for descriptive attributes by using frequency analysis as well analyzed for inferential attributes by using the χ^2 and Fisher exact tests, and bivariate logistic regression when appropriate. A predictive model of adherence was formulated by using linear regression and analysis of marginal means. This study was determined to be exempt from ongoing review by the UM Medical School Institutional Review Board under a waiver for quality assurance and/or quality improvement research.

RESULTS

A total of 320 AIT extract vials labels were reviewed, 238 of which were from patients from independent prescribers and 82

belonged to patients from UM-affiliated prescribing physicians with university-formulated IT extracts. These 82 patients were restricted from analysis because all the vials were adherent to all aspects of the latest practice parameter labeling guidelines.⁵ The characteristics of the prescribing physicians are summarized in Table I. Of 238 non-UM formulated AIT extract vials, 65.5% (n = 156) had 2 PIs, of which 91.7% (n = 143) included the patient's name and date of birth, and 8.3% (n = 13) included the patient's name and medical record number. Other identifiers used included the prescribing physician's name (n = 86), clinic's name (n = 21), barcode (n = 1), lot number (n = 1), and the patient's picture (n = 3). For extract concentration labeling, 62% of the vials (n = 148) had a v/v concentration, 41% (n = 98) were color coded, and 2% (n = 4) were alphanumerically coded. In terms of extract content labeling, 71% (n = 169) of the labels had allergen content listed, of which 64% (n = 108) had the content fully written and 36% (n = 61) abbreviated (eg, T for trees, G for grass). Finally, all the labels analyzed had a recorded expiration date. Only 20.6% of the 238 non-UM formulated AIT extract vials had a complete label, which, per the 2011 practice parameters,⁵ indicated that the following elements were necessary: 2 PIs, the concentration of the vial in v/v format, allergen content and expiration (or beyond use date), and either color or alphanumerically coding as per guidelines recommendations (Figure 1).

Labels with 2 or more PIs had 3.8 times higher odds of having both a v/v concentration with its corresponding color coding (odds ratio [OR] 3.8 [95% CI, 1.9-7.7]; $P < .001$). Labels that specified the extract's content had higher odds to have a v/v concentration listed (OR 3.8 [95% CI, 1.8-7.9]; $P < .001$) and had 6 times higher odds to be either color coded or to have a v/v concentration listed (OR 6.3 [95% CI, 3.4-11.8]; $P < .001$) AIT extract vials that were color coded and had a complete label had higher odds of having clear buildup schedule (OR 12.6 [95% CI, 4.4-35.9]; $P < .001$) provided in the corresponding patient chart and were more likely to have clear instructions about dosing adjustment after a missed AIT injection (OR 8.2 [95% CI, 3.2-21.5]; $P < .001$) and after a systemic reaction (OR 12.7 [95% CI, 7.2-22.4]; $P < .001$). These vials also were at 10 times higher odds to have clear instructions about how to treat a systemic reaction (OR 9.7 [95% CI, 2.9-32.6]; $P < .001$) (Table II).

An additional, prespecified analysis was targeted toward exploring the relationship between labeling content adherence and years in practice. Time in practice was previously identified as a factor that is influential of adherence and adherence with guidelines.¹²⁻¹⁶ When we adjusted for AIT extract vials labels that have both 2 PIs and allergen content listed, the predicted probability of having both a v/v concentration on the label and the AIT vial being color coded decreased by 4% for every year in practice of the respective prescribing physician (Figure 2).

DISCUSSION

AIT has been a staple and distinguishing feature of clinical allergy practice for more than a century.¹ The first clinical practice guidelines for AIT were only recently published, in 1994,² but have been updated 3 times in the past 20 years, most recently in 2011.⁵ Within this time frame, there have been comprehensive recommendations to the practice of AIT that include the use of standardized dosing regimens for selected

TABLE I. Characteristics of the AIT prescribing physicians: characteristics of the nonuniversity prescribing physicians (n = 114)

	No.
Specialty of prescribers	
Allergy	107
Otolaryngology	7
Location of practice	
Michigan	55
Out of state	59
Allergy/immunology board certified	
Certified	102
Noncertified	12
No. years in practice	
≤10 y	20
>10 y	94

antigens, more-efficient mixing processes that minimize the effects of protease on extract stability, better classification and monitoring of systemic reactions, use of concentrate for maintenance extracts, and comprehensive, standardized labeling guidelines to enhance communication and improve safety. These guidelines changes have been positioned to enhance AIT clinical outcomes, and there remains a continued push to further standardize the AIT process to improve patient safety and improve communication among health care providers.

Although much of the focus of AIT practice improvement is globally targeted at the reduction and prevention of systemic reactions to immunotherapy,^{11,17,18} there are many potentially overlooked areas of importance, such as patient outcomes related to the safety of extract mixed by an allergist but administered at a nonallergist's office because of patient-level convenience and logistical factors. This is a common occurrence that arises secondary to access to care issues or for convenience to the patient and results in allergy extracts that are prepared by specialists are subsequently administered in the offices of primary care physicians or specialists or other health service facilities. These practices may not know one another, and the practice of administering the AIT likely does not have familiarity with interoffice notation or a convention "style" that may be regularly used for AIT in the specialist office. Such jargon or inside familiarity may not translate to the external practice.

These aspects may be neglected when AIT is distributed to that outside practice for administration. For universities and other institutes of higher learning, it is a relatively common occurrence to accommodate students from outside the area to allow students to continue already established therapy. Differences in labeling of AIT extracts can potentially lead to increased confusion and possible errors for health care personnel who administer the AIT, especially in the setting of a campus health service that may not also have a specialty allergy clinic or experienced AIT nursing to administer injections. However, to our knowledge, there is no literature that describes labeling adherence or the ramifications that could occur as a result.

This study was exploratory, to investigate the extent to which labeling variation may occur. Our site was ideal for this because we have a robust UHS allergy service for AIT, a large number of prescribers external to the university over which to explore prescribing variation, and have a criterion standard control population of n = 82 internally written AIT prescriptions that were

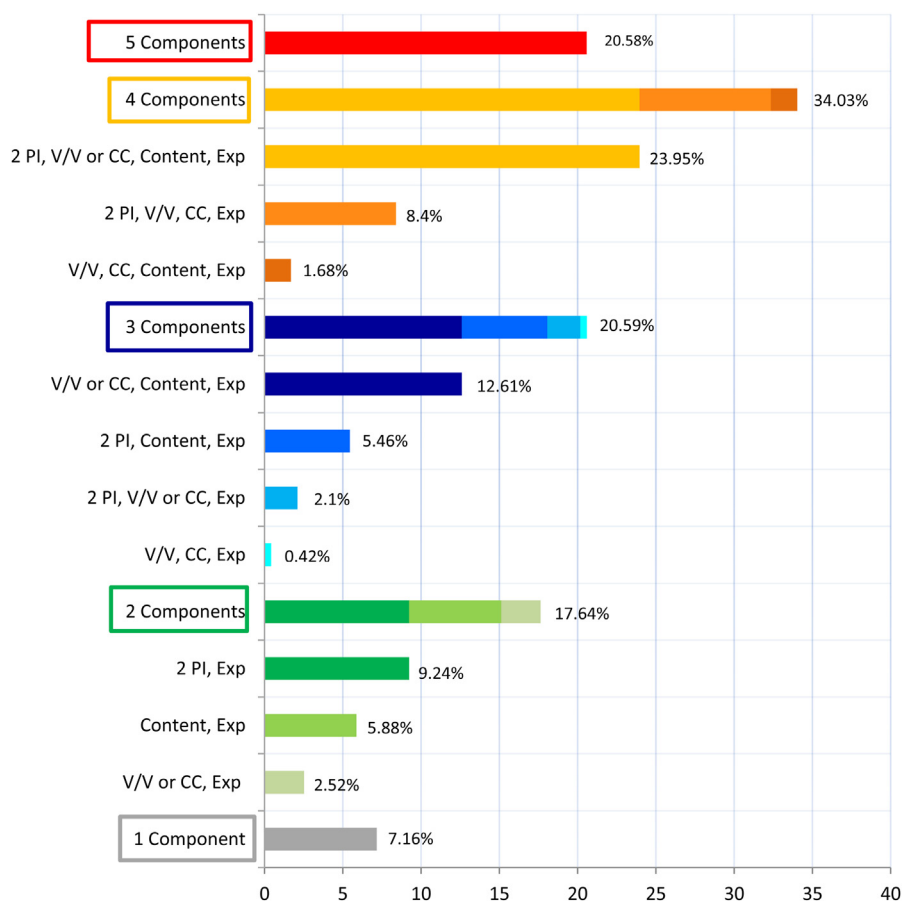


FIGURE 1. Number of recommended label components. CC, Color coding; Exp, expiration date.

TABLE II. Trends of AIT extract vials labeling, dosing, and treatment instructions

Trend	OR	95% CI	P
If 2 PIs were present			
v/v listed	2.2	2.3-3.8	.005
Color coding present	2.8	1.6-5.1	.001
Had both v/v and color coding	3.84	1.9-7.7	<.001
If content present			
v/v listed	3.8	1.8-7.9	<.001
Color coding present	11.2	1.5-84.5	.019
Had either v/v or color coding	6.3	3.4-11.8	<.001
If a complete label was present, then clear instructions about the following also were present			
Clear dosing buildup schedule	12.6	4.4-35.9	<.001
Adjustment for missed dose	8.2	3.2-21.5	<.001
Instructions for treatment of a reaction	9.7	2.9-32.6	<.001
Dosing adjustment after a reaction	12.7	7.2-22.4	<.001

100% adherent to the latest practice parameter recommendations for comparison of effect. Overall there are limited data regarding allergist adherence with any of the updated practice parameter guidelines in the past 11 years. However, there are no previous data, in particular, with respect to vial label guideline

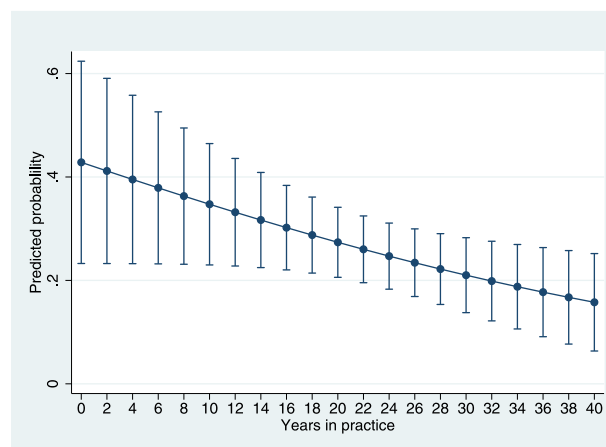


FIGURE 2. Predicted probability of color coding and v/v concentration labeling compliance. Relationship between compliance with allergen extract labels that contain both color coding and v/v concentration information as a function of number of years of practice. Error bars represent 95% CIs.

adherence and the proxy experience in administering AIT written by an outside office.

In the UHS population of AIT written by external providers, we found that fewer than 25% of AIT prescribers were adherent

to AIT practice parameter guidelines as reflected by the high number of incomplete labels reviewed compared with 100% of AIT prescriptions written by UM Division of Allergy and Clinical Immunology faculty. These issues raise concern for patient safety when considering that we showed a strong association between having labels with 2 or more PIs and both v/v concentration and color coding (what we declared a “completely adherent” label) and adherence to other safety measures, such as having instructions about how to modify the dosage schedule if the patient does not adhere to the recommended buildup schedule or how to both modify a dose and if a reaction occurs as well as how to treat a reaction. The adherence issue is important because these patients are being provided AIT in a venue that may not be staffed by an allergist and is not a formal allergy office, and, therefore, guidance about how to manage a local or systemic reaction in particular is essential to avoid potentially catastrophic patient-care outcomes.

Perhaps more concerning is analysis of the data that indicates a trend in the odds of adherence with what is considered to be a “complete label” decreased among this prescribing population in a linear fashion by 4% for each year in practice and indicates a fundamental problem in implementation of updated allergy practice parameters for AIT when considering that it has been 11 years since the 2003 recommendations³ for color coding (summary statement 90 in the 2011 practice parameters), and 7 years since the 2007 recommendation⁴ for v/v and 2 PIs on the label (summary statement 87 in the 2011 practice parameters). In addition, this suggests potential problems with adherence to The Joint Commission National Patient Safety Goals that reinforce identification of patients using 2 identifiers.

An alternative explanation may be that established practices continue to use a labeling system that predates the 2003³ and 2007⁴ practice parameters and are still in the process of transition toward the uniform recommended labeling system. Although the practice parameters suggests that transition toward the recommended uniform labeling system should be done gradually to reduce potential errors,⁵ analysis of our data raises concern that such a transition may not even be occurring, given that, 6 to 7 years later most practices were not in compliance.

There are several limitations to this study. The study was exploratory for descriptive differences in adherence to recommendations for labeling and did not investigate if such a lack of adherence, as described, actually led to a higher rate of adverse events. This is a subject presently being studied by our group. Although our patient population transferred their care to UHS from diverse geographic location, it is hard to generalize our 21% adherence rate to providers in other states without further studies. As well, most of our providers have been in practice for >20 years, which may create a bias toward older practice styles, and there are no data of which we are aware, to date, that demonstrate any risk from a lack of adherence.

We have not assessed provider experience or personal views on the parameter updates and have not assessed the effect of provider subspecialty fellowship training on adaption and implementation of new information. The standard for determining the clarity of AIT dosing scheduling instructions, reactions definitions, and treatment instructions was done by our group of academic allergists, and could be considered biased and/or excessive compared with what may be the “community” standard for allergists or otolaryngologists who prescribe AIT (who would not necessarily be inclined to follow American Academy of Allergy,

Asthma & Immunology—American College of Asthma, Allergy & Immunology guidelines). Motivations for adherence or lack thereof and providers’ willingness to make a requested change to labeling also were not considered and are being investigated in an ongoing study. Lastly, UHS does not have a policy to which it holds outside AIT prescribers in terms of what labeling components are expected for extracts administered remotely in the UHS office.

This, to our knowledge, is the first study that explores adherence to AIT extract labeling guidelines and is the first description of remote AIT prescribing behavior in a university health services setting. We note poor adherence with labeling guidelines among the outside prescribers of AIT administered at UHS, and it is worrisome that such variation demonstrated an inversely proportional, linear relationship to time in practice, a specific finding that requires further follow-up study. Such variation highlights the significant potential for adverse events that could result from AIT not labeled to the most current practice parameter recommendations. Analysis of these data indicates that there is considerable room for improvement in adherence to these guidelines, all of which have been recommended for several years. We are conducting an ongoing study to evaluate both provider motivations to comply with guidelines and the effects of labeling variation or poor adherence on dosing errors and adverse events. Adherence with AIT clinical practice is important to patient safety, which is especially important in the practice of administering AIT in settings that are not allergy offices, such sites generally lack robust experience in providing AIT compared with an allergy practice and likely lack direct access to board-certified allergists when issues arise. Therefore, maximizing labeling adherence is even more critical for such settings, given the potential for error that can be made based on any existing variation.

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